Genetics Task Force Subcommittee Three Report

Subcommittee Title: Subcommittee 3 – The Use of Genetic Information in Research
Subcommittee Chair: Peter Byers, M.D.
Subcommittee Members: Helen McGough, Phillip Bereano, JD**,** Amanda DuBois, JD, Vicki Hohner
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I. Background

II. The incidence of discriminatory actions based upon genetic information

A. Findings

1. The Washington State Human Rights Commission (WSHRC) has received no reports of discriminatory actions based on the results of genetic studies from research activities occurring in Washington.
2. The University of Washington IRB has received no complaints of such behavior as a consequence of research performed under its aegis.
3. The Washington State Human Rights Commission (WSHRC) has the authority to investigate claims of discrimination based on genetic information and to punish violators if evidence supports the claim (RCW 49.60). Lawsuits may also be filed under the ADA if genetic discrimination occurs. Criminal and civil penalties may be assessed if violations are proven. The scope of this protection is unclear.
4. When research data are considered as part of "medical information" they derive all aspects of protection afforded those data from State and Federal laws and regulations.
5. There is a formal reporting system for perceived abuses that occur to a subject in the course of subject participation in research covered by federal regulations (45 CFR 46). This pathway is by the subject and through the principal investigator and/or the Investigational Review Board (IRB) that evaluated the proposal for human subjects research, or directly to the Federal oversight agency e.g., Office of Human Research Protection (OHRP) or the US Food and Drug Administration.
6. There is no required reporting system for un-regulated research.

B. Conclusions

Based on evidence received we conclude that:

1. RCW 49.60 and RCW 70.02 substantive legal protection against discrimination based on use of genetic information (regardless of the source)
2. Gaps in protection exist that may leave research subjects vulnerable to the misuse of genetic information obtained in research, if that information would have to be reported by the subject to insurers, employers, or others who may make decisions on the basis of that information and use it in an adverse fashion for the individual.
3. Predictive test results in the absence of a current diagnosis made by clinical examination, whether derived as part of clinical testing or from research studies,

cannot be requested or used by an insurer in making a decision about insurability WAC 284.43.720).

4. No existing legislation addresses the type of genetic information an insurance company or employer may request and expect to receive from an individual or limits subsequent disclosure, unless this information is considered as "medical information" in the context of RCW 49.60 and RCW 70.02.
5. There are no external mechanisms to monitor compliance with the ADA or RCW 49.60, which leaves the responsibility to report violations to subject or witnesses who feel genetic information may have been used in an adverse fashion.

C. Recommendations

We recommend that:

1. The Legislature authorize the funding of efforts by the Department of Health to educate consumers, research subjects, researchers, health care providers, employers, and insurers about how genetic information derived from DNA sequences, as part of medical information, can be used, the concepts and consequences of anonymity in research, and on the reporting and other mechanisms available to those who believe they have been discriminated against.

III. Strategies to safeguard civil rights and privacy related to genetic information

A. Findings

1. Several layers of legislation exist to safeguard civil rights and privacy related to genetic information used for or generated by research including federal HIPAA regulations, the Washington State Uniform Health Care Information Act (RCW 70.02), 45 CFR 46 and 21 CFR 50/56. Researchers may also apply for a federal certificate of confidentiality that protects them from court-ordered disclosure of research data under most circumstances. No direct enforcement mechanism is in place for HIPAA or RCW 70.02. As a result, regulatory agencies must rely on reports of violations rather than inspections. Institutional Review Boards (IRBs) and research projects regulated by the U.S. Food and Drug Administration (FDA) under 21 CFR 50/56 are subject to routine inspections for compliance and have extensive reporting responsibilities to parent agencies.
2. Genetic research activities conducted without federal financial support, in facilities that have not voluntarily adopted the federal protections, and that do not involve FDA-regulated test articles are not required to conform to and follow legal requirements and standards established for the involvement of human subjects in research.
3. According to federal law, different research study designs require different levels of informed consent. For example, research using biological samples from which all information that could identify the individual from whom they were obtained has been removed ("anonymized" samples) may not require informed consent of the individuals from whom they were obtained. However, research using samples that maintain information from which the donor can be identified almost always requires the consent of the individual who originally provided the information or biological sample.

B. Conclusions

Based on information provided we conclude that:

1. The majority of the members of this committee thought that existing federal and state legislation provide substantial protection with respect to the privacy and civil rights of research subjects
2. Knowledge of existing laws that protect privacy and civil rights may encourage people to participate in genetic research.
3. Waivers of consent for research on previously obtained tissues or samples are appropriate for some types of research under current Federal regulations.
4. Appropriate monitoring/oversight systems are lacking for research on human subjects in some settings.

C. Recommendations

We recommend that:

1. Research involving human subjects in the State of Washington be subject to the standards that are in place for federally funded human subjects research
2. Researchers, subjects, health care providers, insurers, and employers have access to all existing laws that protect the privacy of medical information, including DNA-based information.
3. State policies leave the responsibility of monitoring research activities that involve human subjects to IRBs
4. A minority of the committee members recommended that the Legislature of the State of Washington propose and enact legislation (either as new legislation or as amendments to existing statutes) that explicitly defines genetic discrimination, genetic information, and privacy rights of individuals with respect to genetic information.

IV. Remedies to compensate individuals for inappropriate use of genetic information

A. Findings

1. Existing laws such as HIPAA, ADA, RCW 70.02, and RCW 49.60 contain provisions for criminal and/or civil penalties in the case of violations including privacy violations and discrimination.
2. Researchers and institutions housing researchers found to be in violation of federal regulations are subject to fines, suspension of research activities or loss of federal funding. They may also be sued by individuals who claim wrongdoing.

B. Conclusions

We conclude that:

1. The majority of the committee concluded that existing penalties for the violation of laws protecting the privacy and civil rights of individuals who provide genetic information for research purposes are adequate.
2. A minority concluded that these laws were inadequate.

C. Recommendations

We recommend:

1. The majority of the committee recommended that no further action be taken by the state**.**

2. A minority of the committee recommended that, as has been done in many other states, Washington pass legislation that protects the privacy of genetic information, defines and outlaws genetic discrimination and provides avenues for redress whether violations are proven.

V. Incentives for further research and development on the use of DNA to promote public health, safety and welfare

A. Findings

1. Genetic research will contribute to the development of understanding of many aspects of human biology. and tools for medical care including diagnosis, disease prevention, and treatment.
2. Currently many genetic tests exist, but the knowledge needed to apply many of them in a clinical setting–eg, significance of outcomes, consequences, etc-- is lacking.
3. Development of genetic tests/technologies and some pharmaceuticals requires access to DNA samples.
4. Anonymous samples are not always adequate for research purposes. For example, identifiers are needed to match clinical data with genotype data.
5. Genetic research aimed at associating genotypes with phenotypic profiles may be important to advance medical and public health knowledge including screening programs, education/intervention programs, and therapies.

B. Conclusions

We conclude that:

1. The development of genetic tests far outpaces the availability of information and personnel to interpret and apply the test results in a health care setting. In the current health care environment the costs for making genetic testing available, as a result of research and development studies, may impede equitable availability of such resources to all segments of our population.
2. Research studies that use identifiable DNA samples or anonymous DNA samples are among types of biomedical research important for the advancement of medical and public health knowledge and may provide benefits to the citizens of Washington.
3. Academic and private researchers receive adequate incentives to conduct genetic research.

C. Recommendations

We recommend that:

1. In all research that involves genetic information from individuals explicit voluntary consent or assent should be obtained, as detailed in current applicable law and regulations.